biodenta®

K111003

SEP 15 2011

5

510(k) Summary

Owner's name:	Biodenta Swiss AG
Address:	Tramstrasse 16 9442 Berneck Switzerland
Phone:	+41 71 747 11 11
Fax number:	+ 41 71 747 11 12
Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	April 8, 2011
Trade / proprietary name:	Biodenta Dental Implant System - Bone Level
Common name:	Endosseous dental implant
Device classification name:	implant, endosseous, root-form
Product code:	DZE
Regulation number :	21 CFR 872.3640
Subsequent Product Code:	NHA (Regulation number: 21 CFR 872.3630)

Legally marketed device to which equivalence is claimed (predicate device):

Company:	Biodenta Swiss AG
Device name:	Biodenta Dental Implant System
510(k) number:	K093630
Company:	Nobel Biocare Ab
Device name:	Nobelactive Internal Connection Implant
510(k) number:	K071370

biodenta®

K111003

Indications for Use:

Biodenta bone level dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Device Description:

The Biodenta Dental Implant System – Bone Level is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments and prosthetic parts and related surgical instruments.

Non-clinical Testing Data:

Fatigue testing was conducted according to FDA Guide: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff and ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants. The worst case scenario for the Biodenta Dental Implant System - Bone Level implants and abutments was tested. These results show that Biodenta Dental Implant System - Bone Level have sufficient mechanical strength for their intended clinical application.

Equivalence to marketed device:

Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Dental Implant System - Bone Level is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the Biodenta Dental Implant System - Bone Level.

biodenta®

K111003

Substantial Equivalence Comparison to predicate device:

	Subject Device	Predicate Devices	
Device	Biodenta Dental Implant System - Bone Level	Biodenta Dental Implant System (K093630)	Nobelactive Internal Connection Implant (K071370)
Intended use	Biodenta bone level dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures. Specific indications for small diameter (Ø 3.5 mm) implants: It is recommended not to place small implants with "NP" platform in the molar or premolar region.	Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.
System	threaded, root-form dental implant, bone level	threaded, root-form dental implant, tissue level	threaded, root-form dental implant, bone level
Diameter	3.5 mm, 4.1 mm, 4.8 mm	3.5 mm, 4.1 mm, 4.8 mm	3.5 mm, 4.3 mm, 5.0 mm
Connection	Internal Hexagon	Internal Octagon	Internal Hexagon
Implant Material	Titanium	Titanium	Titanium
Abutment System	Angled Abutment	Angled Abutment	Angled Abutment
Abutment Angle	0°, 15°	0°, 15°, 20°	0°, 15°
Abutmet Material	Titanium Alloy	Titanium Alloy	Titanium Alloy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David Eiler
Regulatory Manager
Biodenta Swiss AG
Tramstrasse 16
9442 Berneck
Switzerland

SEP 15 2011

Re: K111003
Trade/Device Name: Biodenta Dental Implant System – Bone Level
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 9, 2011
Received: September 12, 2011

Dear Mr. Eiler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

biodenta®

Indications for Use

510(k) Number (if known): K111063

Device Name: Biodenta Dental Implant System - Bone Level

Indications for Use:

Biodenta bone level dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111003